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K012298

Cerium Optical Technologies, Inc.

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Contact: Sol Aisenberg, Ph.D.

Premarket Notification - 510(k) Summary

Date: June 30, 2001

Device Name: Lens, Spectacle, Tint, Color Selector

TRADE NAME - The Intuitive Colorimeter

COMMON NAME – Color Illuminator

CLASSIFICATION NAME - Color Vision Illuminator - Ophthalmic Devices

EQUIVALENT DEVICES:

This device is similar to a Color Vision Plate Illuminator (886.1160).

DESCRIPTION OF THE DEVICE:

A spectacle Lens Tint Color Selector is an AC powered device that is a variable illumination box intended to simulate vision through different colors of spectacle lens tints for the purpose of selecting preferred tint(s).

The device is a variable color illuminator and is intended as an aid in the selection of tinted spectacle coatings. It provides illumination that simulates visual perception through various colors of tinted spectacles,

The Intuitive Colorimeter uses light produced by a fluorescent tube, and the light is passed through a filter drum composed of seven colored filters. These filters consist of the 7 positions. The light is then viewed through a window in the instrument.

When the drum is moved or rotated, the light becomes colored. Neutral density filters can adjust the luminance. Thus there are four calibrated controls, one for hue (color), one for saturation (depth), and one for the neutral density filter, plus a control that permits white fluorescent light to be substituted, for the purpose of base line evaluation.

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INTENDED USE OF DEVICE:

The device is designed to be used to specify the Cerium precision tinted CR39 lenses provided by Cerium Visual Technologies in England. These lenses are precision tinted to correspond to the values determined by the Colorimeter, and are tested and certified before shipment by Cerium Visual Technologies in England to the licensed professional.

The device will help to determine spectacle tints that are preferred by users. These tints may be selected for cosmetic reasons, or to reduce visual stress or visual discomfort.

The device will only be used under the control of licensed Optometrists and Ophthalmologists and to be used with subjects having proper vision, or corrective lenses if necessary.

The filter values and refractive lens values are then provided to Cerium Visual Technologies in England who will then provide the corrective lenses with the necessary tinted values. A certificate of testing is provided with the precision tinted lenses.

The Intuitive Colorimeter permits the subject to conveniently determine the better combinations by use of the adjustment and variable controls on the device until the subject and operator determine which combination is good for the subject. This is done without the need for use of a limited selection of tinted lenses or color overlays. At the same time, the Intuitive Colorimeter produces the tint specification values selected by the user. These values are then used by Cerium Visual Technologies in England to prepare the precision tinted lenses. These lenses will also include the optical corrective values as determined by an associated eye examination made by the ophthalmic professionals using the Intuitive Colorimeter.

The device is intended to be used to specify the Cerium precision tinted CR39 lenses provided by Cerium Visual Technologies in England. These lenses are precision tinted to correspond to the values determined by the Colorimeter, and are tested and certified before shipment by Cerium Visual Technologies in England to the licensed professional. Note that Cerium Optical Technologies, Inc. in the USA is owned by Cerium Visual Technologies in England.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS:

The Intuitive Colorimeter uses light produced by a fluorescent tube, and the light is passed through a filter drum composed of seven colored filters. These filters consist of the 7 positions. The light then falls on a page of text that the subject views through a window in the instrument.

When the filters are removed from the light path by drum rotation the resulting illumination is white light. The light intensity in the viewing area is less than in a classroom. When the filter drum is moved, the light becomes colored. Changing the drum position changes saturation (depth) of the color, changes the color (hue), and changes the luminance. There is a control that permits white fluorescent light to be substituted, for the purpose of base line conditions before preferred tints are selected.

The device is designed to specify the Cerium precision tinted CR39 lenses provided by Cerium Visual Technologies in England. These lenses are precision tinted to correspond to the values determined by the Colorimeter, and are tested and certified before shipment by Cerium Visual Technologies in England to the licensed professional who specifies the lens characteristics.

NON-CLINICAL PERFORMANCE:

The use of the device and the selected tinted spectacle lenses may be helpful to subjects who can benefit from reduced visual stress and reduced visual discomfort. When precision tinting is provided on any necessary corrective lenses, the combination can help users.

The Intuitive Colorimeter is designed to provide improved selection of tinted spectacle lenses with the use of CONTINUOUSLY variable light, rather than just the evaluation with a limited selection of tinted lenses. The Intuitive Colorimeter provides stable and calibrated illumination of text with variable light. It permits the mixing of light with independent continuous control of hue (color), saturation (depth of color), and luminance (brightness, illumination). Precision tinted lenses for each subject can then be made to correspond to the values selected by the subject using the Intuitive Colorimeter.

We intend to make the Intuitive Colorimeter and precision tinted lenses also available to help the trained professionals and to make their work easier in many cases.

It is hoped that the above material will be sufficient to demonstrate the safety and effectiveness of the Intuitive Colorimeter so that the device and technology can be made available to also help persons in the United States.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 6 2001

Sol Aisenberg, Ph.D.
Technology and Business Advisor
Cerium Optical Technologies, Inc.
12 Albert Street, Suite 300
Woburn, MA 01801

Re: K012298
Trade/Device Name: The Intuitive Colormeter
Regulation Number: 21 CFR 886.1160
Regulation Name: Color vision plate illuminator
Regulatory Class: I
Product Code: NFD
Dated: July 30, 2001
Received: July 20, 2001

Dear Dr. Aisenberg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510 (k) NUMBER (IF KNOWN): ___K012298_____

DEVICE NAME: __Lens, Spectacle, Tint, Color Selector_____

INDICATIONS FOR USE:

A Spectacle Lens Tint Color Selector is an AC powered device that is a variable-color illuminator box intended to simulate vision through different colors of spectacle lens tints for the purpose of selecting preferred tint(s).

Daryl Lough

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K012298

(PLEASE DO NOT WRITE BELOW THE LINE-CONTINUE ON ANOTHERR PAGE IF NEEDED.)

Concurrence of CDRH, office of Device Evaluation (ODE)

Prescription Use ___X___ or Over-The-Counter Use
(Per 21 CER 801.190)